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EXAMINER

HELMS, L

ART UNIT

PAPER NUMBER

1642

DATE MAILED:

07/19/01

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/016,743

Applicant(s)

Rosenblatt et al

Examiner
Larry R. Helms Ph.D.

Art Unit
1642



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 May 2001
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-76 is/are pending in the application
- 4a) Of the above, claim(s) 11-24 and 26-76 is/are withdrawn from consideration
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-10, and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirements

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☒ The proposed drawing correction filed on 16 Aug 2000 is: a) ☒ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

Art Unit: 1642

DETAILED ACTION

1. Claims 1, 3-76 are pending.

Claims 1, 3-6, 8-9 have been amended.

Claims 11-24 and 26-76 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention, the requirement having been traversed in Paper No. 7.

Claims 1, 3-10 and 25 are under examination.

2. The text of those sections of Title 35, U.S.C. Code not included in this Office Action can be found in a prior Office Action.

Rejections Withdrawn

3. The rejection of claims 1-10 and 25 under 35 U.S.C. 112, second paragraph, in the previous Office Action of paragraph 9d, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendments to the claims.

4. The rejection of claims 1-10, and 25 under 35 U.S.C. 112, first paragraph, is withdrawn in view of the amendment to the claims.

Response to Arguments

Art Unit: 1642

5. The rejection of claims 1-8, 10 and 25 under 35 U.S.C. 103(a) as being unpatentable over Holzer et al (U.S. Patent 5,824,782, filed 9/15/95) and further in view of Huston et al (Meth. Enzymol. 203:46-88, 1991) is maintained.

The response of 5/10/01 has been carefully considered but is deemed not to be persuasive. The response states that Holzer does not satisfy the requirement of the claimed invention that the chemokine be "coupled to the N-terminus of the heavy or light chain of the antibody" and "one of ordinary skill in the art would not adapt the teaching in Huston to Holzer because it would undermine Holzer's expressed command that the entity attached to the antibody be bound at its N-terminus" and "the claims of the present application (and the disclosure of Holzer) call for an antibody as opposed to a single-chain Fv molecule" (see page 4 of response). In response to these arguments, Holzer specifically teach that the N-terminal of IL-8 is required for receptor binding, therefore it would be obvious that one would conjugate the IL-8 to a heavy or light chain as taught by Huston by conjugating the c-terminus of IL-8 to the N-terminus of the light or heavy chain. Furthermore, Holzer et al specifically teach antibodies containing constant regions as well as an Fv molecule (see Figure 1), therefore, it would be obvious that one would combine the teaching of Huston with Holzer and apply it to entire antibodies as taught by Holzer. In addition, the specification teaches the term "Antibodies" as including antibody fragments such as Fab and Fv fragments (see page 22-23). In addition the claims are not limited to an intact antibody comprising a VH, VL, CH1, CL, CH2, and CH3.

Art Unit: 1642

6. The rejection of claims 1, 3-10 and 25 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained.

The response filed 5/10/01 has been carefully considered but is deemed not to be persuasive. The response states that the claims have been amended to recite "an antibody". In response to this argument, it is still unclear what defines the "N terminal". Is a protein that has an N terminal methionine processed off not included in the claims?

7. The rejection of claims 1 and 9 under 35 U.S.C. 103(a) as being unpatentable over Huston et al (Meth. Enzymol. 203:46-88, 1991), and further in view of Bacus (U.S. Patent 5,514,554, filed 10/7/93) and Holzer et al (U. S. Patent 5,824,728, filed 9/15/95) is maintained.

The response filed 5/10/01 has been carefully considered but is deemed not to be persuasive. The response states Bacus does not overcome the above-noted deficiencies of Holzer and Huston. In response to this argument, the response to Holzer and Huston has been presented above. Bacus is cited for teaching monoclonal antibodies to her2/neu conjugated to therapeutic agents which are obvious in view of Holzer and Huston.

Conclusion

8. No claims are allowed.

Art Unit: 1642

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (703) 306-5879. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

11. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal

Application/Control Number: 09016743

Page 6

Art Unit: 1642

Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-7401.

Respectfully,

Larry R. Helms Ph.D.

703-306-5879


SHEELA HUFF
PRIMARY EXAMINER